SUCTION UNIT NEW EMIVAC

USER MANUAL

CE 0123

www.medicalsuction.co.uk

NEW EMIVAC it's a manual device to be used for the emergency field to be used for the aspiration of the body liquids (mucus or catarrh or blood). Easily movable and designed for a manual use.
Thanks to this characteristics and to the rating that it has product is particularly suitable for a emergency use, on the thacheotomized patients, minor surgical applications and post - operative therapy at home.
Made of highly heat resistant, in conformity with the latest European safety standard, the product is supplied with a polycarbonate 0.4 litre autoclavable jar with overflow valve.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

ONLY HIGHLY QUALIFIED STAFF USE RESERVED

THE INSTRUMENT MUST NOT BE DISASSEMBLED. FOR A TECHNICAL SERVICE ALWAYS CONTACT CA-MI

IMPORTANT SAFETY RULES

1. Check the condition of the unit before each use.
2. Respect the safety regulations indicated for electrical appliances and particularly:
· Use original components and accessories provided by the manufacturer to guarantee the highest efficiency and safety of the device;
· The device can be used only with the bacteriological filter;
· Place instrument on stable and flat surfaces;
· Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
· Keep off the reach of children or not capable people without supervision;
· Preserve and use the medical device in environments protected from atmospheric factors and at a distance from heat sources;
· Don't use the device thoracic drainage.
3**.** For repairs, exclusively contact technical service and request the use of original spare parts.
Failure to comply with the above can jeopardise the safety of the device;
4. **Use only for the purpose intended.** Don't use for anything other than the use defined by the manufacturer.
The manufacturer will not be responsible for damage due to improper use.
5. Instrument and accessory discharging must be done according to current regulations in the country of use.
6. None of mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact technical assistance
7. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same.

The manufactured cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse.

Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance
with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2002/96/EC:

In respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 “Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal”
The symbol as over applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of device useful, the user will must deliver it to the able collecting centres for electric and electronic garbage, or give back to the retailer in the moment of equivalent new device purchasing, one against one. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of witch it’s made up in order to obtain an important saving of energy and resources and to avoid negative effects to the ambient and health. In case of abusive disposal of device by user, will be applied administrative endorsements in compliance with current standard.

TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Medical Device Class II a
MODEL	**NEW EMIVAC**
CLASSIFICATION UNI EN ISO 10079-1	MEDIUM VACUUM / 22l/min
MAXIMUM SUCTION PRESSURE (without jar)	-40kPa (- 0.40 bar)
MAXIMUM SUCTION FLOW (without jar)	22 l/min
WEIGHT	1.15 Kg
SIZE	225 x 165 (h) x 85 mm
SICILICONE TUBE SIZE	Ø 6 x 10 mm
ACCURANCY OF VACUUM INDICATOR	± 5%
WORKING CONDITION	Room temperature: 5 ÷ 35°C Room humidity percentage: 30 ÷ 75% RH Altitude: 0 ÷ 2000m s.l.m.
CONSERVATION CONDITION AND TRASPORT	Room temperature: -40÷ 70°C Room humidity percentage: 10 ÷ 100% RH

SYMBOLS

	Class II isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	Warning, consult the instruction manual
	Keep in a cool, dry place
	Conservation temperature: -40 ÷ 70°C
	Type B equipment
	DEHP Phthalates (Suction catheter)

ACCESSORIES SUPPLIED

DESCRIPTION
COMPLETE ASPIRATION JAR 400cc
CONICAL FITTING
TUBES SET 6 mm x 10 mm
HYDROPHOBIC AND ANTIBACTERIAL FILTER

The filter is produced with (PTFE) hydrophobic material to prevent fluids entering the pneumatic circuit.
It should be changed immediately if it becomes wet or if there is any sign of contamination or discolouration.
If should also be changed if the unit is used with a patient whose risk of contamination is unknown.
Don't use the suction unit without the protection filter. If the suction unit is used in an emergency or in a patient where the risk of contamination is not know the filter must be changed after each use.

WARNING: Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.

WARNING: The medical device is provided without a specific suction probe. If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the EN 10079-2 regulation.

WARNING: Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.

CLEANING OF ACCESSORIES

To clean the plastic housing of the device wear disposable latex gloves and clean with denaturated alcohol or hypoclorite solutions. Washing and / or cleaning the autoclavable jar as to be carried out as follows:
· Wear protection gloves and apron (glasses and face mask if necessary) to avoid contact with contaminating substances;
· Disconnect the jar from the device
· Disconnect all tubes from the jar and the protection filter
· Empty and dispose of the Jar according to the laws in force in your country;
· Separate all parts of the cover (overflow valve, o-ring);
After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thouroughly.
Then soak in warm water (temperature shall not exceed 60°C). Wash thouroughly and if necessary use a non-abrasive brush to remove incrustations. Rinse in running warm water and dry all parts with a soft cloth (non-abrasive).
The jar and the cover can be autoclaved by placing the parts into the autoclave and running one sterilization stem cycle at 121°C (1 bar relative pressure) making sure that the jar is positioned upsidedown.
Mechanical resistance of the jar is guaranteed up to 30 cycles of sterilization and cleaning at the indicated conditions (EN ISO 10079-2). Beyond this limit the physical-mechanical characteristics of the plastic may decrease and replacement of the part is therefore recommended.
After sterilization and cooling at environment temperature of the parts make sure that these are not damaged.
Assemble the jar as follows:
· Place the overflow valve into its seat in the cover (under VACUUM connector)
· Insert floating valve keeping the o-ring towards the opening of the cage
· Place the o-ring into its seat around the cover
· After completing assembling operations always make sue that cover seals perfectly to avoid vacuum leackages or liquid exit
The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 120°C. The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C. The device is ready for a new employment now.

DO NOT WASH, STERILIZE OR PUT IN AUTOCLAVE THE ANTIBACTERIAL FILTER

MAINTENANCE

The **NEW EMIVAC** suction equipment does not need maintenance or lubrication.
It is necessary to check functioning and instrument before every use.
Unpack the instrument and **always check** integrity of plastic parts, they might have been damaged during previous use.
Close the aspirator outlet with your finger.
Press the foot and check vacuum functionally.

Fault type	Cause	Solution
1. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
2. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
3.The Vacuum power on the patient side is either very low or absent	● Protection filter blocked or damaged ● Connection tubes blocked, kinked or disconnected ● Shut-off valve blocked or damaged ● Pump motor damaged	● Replace the filter ● Replace or reconnect the tubes, check the jar connections ● Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit twill only work in the upright position ● Refer to authorised service personnel
4. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Insert the float into it's place
5. The float doesn't close	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
6. Low suction	Foam inside the jar	Fill the jar to 1/3 full of ordinary water
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7	**None of the remedies has achieved the desired results**	**Contact the seller or CA-MI After-sales Assistance Service**

If the overfill security system fails, continued aspiration will be stopped by the bacteriological filter.
Should this back-up security also fail, there is a risk of penetration of liquid into the device. Don't attempt to proceed with aspiration under these circumstances.
Return the device to CA-MI for service.

BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE. THE MANUFACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED

INSTRUCTIONS

· Connect the short silicon tube with antibacterial filter to the suction connector
The other tube, with one end connected to the filter must be connected with the other end to the jar's lid connector where has been fixed the red float. When the 90% of the volume of the jar is reached there is the activation of the security float(the float close the aspiration connector on the jar) to avoid liquid penetration inside the device.
The device must be used on a plan of horizontal operation.

WARNING: Ensure that the FLUID SIDE or IN marker on the filter is on the side facing the collection jar lid and fitted into the "VACUUM".A wrong connection causes immediate destruction in case of contact with sucked liquids.

Connect the long silicon tube to the other jar's lid connector
· Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.
· Unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionality vacuum) the rescrew the lid on the jar correctly.
· Push foot to start suction.
· To extract the accessories and start with cleaning as write in the clean chapter

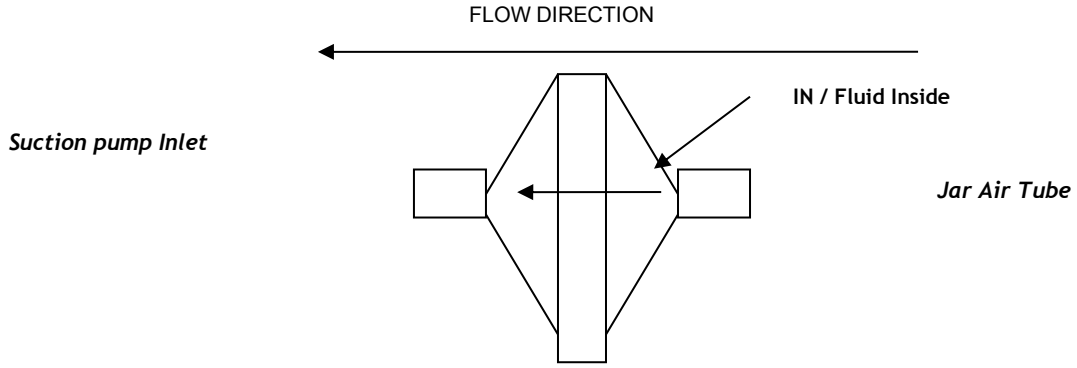
NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE

ALWAYS PLACE THE DEVICE IN POSITIONS FOR EASY DISCONNECTION.

Filter Assembling

Mod: NEW EMIVAC



RULES FOR RETURNING AND REPAIRING

UNDER NEW EUROPEAN RULES, CA-MI REQUIRES THE FOLLOWING PROCEDURES TO BE CARRIED OUT TO PROTECT THE
INSTRUMENT AND THE SAFETY OF ALL WHO COME IN CONTACT WITH IT.

CA-MI warrants it's product for **24 months** after purchasing date.
Before returning an instrument for repair, the external surfaces and all accessories **MUST** be carefully disinfected with a cloth soaked in methylated spirits or hypochlorite-based solution. The instrument and accessories should then be placed in a bag with a note outlining the disinfection undertaken.
Failure to follow this procedure will result in the instrument being returned to the purchaser unrepaired.
Instruments returned for repair **MUST** be accompanied by a description of the problem. CA-MI will not be responsible for damage caused through improper use. To avoid such damage, please read the instruction carefully.
Where CA-MI determines that an instrument is faulty, a replacement will be provided only if a SALES RECEIPT and STAMPED GUARANTEE are provided. CA-MI will not be responsible for damage accessories. These may be replaced at the customer's expence.
CA-MI warrants it's products for **24 months** after purchasing date. In front of this warranty, CA-MI will be obliged only to repair or substitute free of charge the products or parts of them that, after verification effected on our factory, or our authorized Service Center, by the Technical Service, results defective.
The warranty, with exclusion of responsibility for direct and indirect damages, it is thought limited to the solos defects of material or workmanship and it stops having effect when the device results however gotten off, tampered or sheltered out of the Factory or from the Authorized Service center.
The commodity always travels to risk and danger of the buyer, without any responsibility of CA-MI for damages caused by the transport or dismay from the vector.